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STITZEL, DAVID PAUL	
ART UNIT	**PAPER NUMBER**
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,949	COUARAZE ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

OFFICIAL ACTION

Acknowledgment of Receipt

Receipt of the Applicants' Response, which was filed on August 17, 2006, in response to the Official Action dated August 4, 2006, is acknowledged.

Status of Claims

Claim 2 was canceled, and claims 1, 3, 7, 10 and 11 were amended, by an amendment that accompanied the aforementioned Response. As a result, claims 1 and 3-16 are therefore examined herein on the merits for patentability.

Specification Objection

The instant specification as originally filed stands objected to, as the following guidelines illustrate the preferred arrangement, format or layout for the specification of a utility patent application. These guidelines are suggested for the Applicants use.

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs); or REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a); "Microfiche Appendices" were accepted by the Office until March 1, 2001).
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

Claim Rejections - 35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112, which forms the basis of the claim rejection as set forth under this particular section of the Official Action:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. The rejection of claim 11 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, is hereby withdrawn in light of the instant claim amendments deleting the claim recitation of a "compression premix" and inserting in place thereof, a "tableting premix," which is supported in the specification as originally filed (page 14, lines 5-10).

2. Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim as amended introduces new matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. More specifically, claim 1 recites, in relevant part, "wherein said neutral microgranules are ... granules comprising between 62.5 and 91.5% of sucrose ...." Although Applicants provide the United States Pharmacopoeia (USP) definition of neutral microgranules as comprising between 62.5 and 91.5% of sucrose (page 7, lines 18-22) during a discussion of the prior art in what would be considered to be the "Background of the

Invention" section of the instant specification (see the specification objection hereinabove), Applicants became their own lexicographer when, during the written description of the instant invention (page 10, lines 32-37), Applicants explicitly defined "neutral microgranules" as being understood to mean, in the context of the instant invention, spherical granules comprising "less than 91.5% of sucrose," which is not the same as, and thus different in scope from, "between 62.5 and 91.5% of sucrose," as defined by the USP, thereby resulting in the addition of new matter. Where an explicit definition is provided by the Applicant for a term, that particular definition will control the interpretation of said term as it is used in a claim. See MPEP §§ 2111.01 IV, and 2173.05(a) III. Claims 3-16, which are dependent upon and include all of the limitations of independent claim 1, are therefore likewise rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

1. The rejection of claim 10 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, is hereby withdrawn in light of the instant claim amendments deleting the recitation of "system" from said claim.

Claim Rejections - 35 U.S.C. § 102

1. The rejection of claims 1, 7 and 10 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,489,026 (hereinafter the Yalkowsky '026 patent) is hereby withdrawn in light of the instant claim amendment incorporating the limitations of dependent claim 2 into independent claim 1.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. The rejection of claims 2-6, 8, 9 and 11-16 under 35 U.S.C. § 103(a) as being unpatentable over the Yalkowsky '026 patent in view of U.S. Patent 4,983,399 (hereinafter the Maish '399 patent) is hereby withdrawn in light of the Applicants' instant claim amendments canceling claim 2.

2. Claims 1 and 3-16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 4,489,026 (hereinafter the Yalkowsky '026 patent) in view of U.S. Patent 4,983,399 (hereinafter the Maish '399 patent).

With respect to claims 1, 7 and 10 of the instant application, the Yalkowsky '026 patent teaches a tablet formed by direct compression, wherein said tablet comprises: an inert, pharmacologically acceptable, excipient microparticle suitable as a direct compression vehicle or carrier; and an ultra-low dosage of a pharmaceutically active material uniformly deposited onto said inert, pharmacologically acceptable, excipient microparticle (column 1, lines 5-23; column 3, lines 1-33; column 4, lines 45-54).

The inert, pharmacologically acceptable, excipient microparticle may be composed of lactose, starch and/or talc (column 4, lines 31-45). The pharmaceutically active material is present within said tablet in an amount of less than or equal to 100 μg, particularly less than or equal to 10 μg, and more particularly 1 μg, per 200 mg of excipient (column 2, lines 59-64; column 3, lines 40-42; column 5, lines 59-61). That is, said tablet comprises less than or equal to 0.5 mg/g, and more particularly 0.005 mg/g, of said pharmaceutically active material. Therefore, said pharmaceutically active material is present in an amount of less than or equal to 0.05% by weight, and more particularly less than or equal to 0.0005% by weight, of said tablet, thereby reading on a tablet comprising less than 40 mg/g, less than 1% by weight, and less than 10 mg/g, of active principle, as instantly claimed in claims 1, 7 and 10, respectively.

With respect to claims 1, 3 and 14 of the instant application, the Yalkowsky '026 patent teaches that the maximum mean particle diameter of said inert, pharmacologically acceptable, excipient microparticle having a pharmaceutically active material uniformly deposited thereon is in the range of from about 0.5 μm to about 10 μm (column 6, lines 43-44). The Yalkowsky '026 patent therefore does not explicitly teach a microparticle having a particle size between 100 μm and 2000 μm, between 200 μm and 400 μm, and between 200 μm and 600 μm, as instantly claimed in claims 1, 3 and 14, respectively. However, the Maish '399 patent teaches a free-flowing direct compression microparticulate tableting composition having a mean particle diameter in the range from about 70 μm to about 200 μm (column 1, lines 66-68; column 2, lines 1-5 and 50-54; column 4, lines 26-29 and 38-45; claims 1, 3 and 5). It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the particle size of the microparticle of the Yalkowsky '026 patent, to a larger particle size, as taught by the Maish '399 patent, especially since the Yalkowsky '026 patent explicitly teaches that the upper limit of the total spraying time for spraying

said pharmaceutically active material uniformly onto said inert, pharmacologically acceptable, excipient microparticle is not critical (column 4, lines 16-17). In addition, the Yalkowsky '026 patent teaches that although there are a very large number of microparticles having particle diameters between 0.5 μm to about 10 μm, the variation of the particle diameters is not precisely controllable and is variable up to about 100% for a preferred spraying time of at least about 10 minutes (column 4, lines 7-19; column 6, lines 41-62). Therefore, increased spraying times for spraying said pharmaceutically active material uniformly onto said inert, pharmacologically acceptable, excipient microparticle beyond a spraying time of at least about 10 minutes would result in microparticles having increased particle diameters beyond 0.5 μm to about 10 μm. One of ordinary skill in the art at the time the instant application was filed would have been motivated to modify the particle diameters of the microparticle of the Yalkowsky '026 patent, because not only does the Yalkowsky '026 patent teach that the total spraying time is not critical, but also the Maish '399 patent teaches that a direct compression microparticulate tableting composition having a mean particle diameter in the range from about 70 μm to about 200 μm results in a free-flowing composition, thereby facilitating large scale industrial manufacturing processes and effectuating content uniformity among the manufactured tablets by promoting uniform distribution of the inert components and the medicament (column 1, lines 66-68; column 2, lines 1-5 and 50-54; column 4, lines 26-29 and 38-45; claims 1, 3 and 5).

With respect to claims 8, 9, 11 and 15 of the instant application, the Yalkowsky '026 patent teaches a tablet formed from direct compression of an inert, pharmacologically acceptable, excipient microparticle having a pharmaceutically active material uniformly deposited thereon; wherein said microparticle may comprise starch, lactose and/or talc (column 4, lines 31-45). The Yalkowsky '026 patent does not explicitly teach a particular weight percent of said talc. However, the Maish '399 patent teaches a free-flowing direct compression microparticulate tableting composition comprising: an

inert diluent, such as starch, lactose and the like; an inert lubricant, such as talc, stearic acid, magnesium stearate, calcium stearate, silica and PEG; and a medicament; wherein said lubricant is present in the range from about 0.25% to about 5.0% by weight (column 2, lines 50-54; column 3, lines 3-20 and 42-52; column 5, lines 9-13). It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the microparticle of the Yalkowsky '026 patent, by incorporating an inert lubricant, such as not only talc, but also stearic acid, magnesium stearate, calcium stearate, silica and PEG, in an amount from about 0.25% to about 5.0% by weight, as taught by the Maish '399 patent, especially since the Maish '399 patent teaches the interchangeability of stearic acid, magnesium stearate, calcium stearate, silica and PEG with talc at the aforementioned weight percent range (column 3, lines 3-20 and 42-52). One of ordinary skill in the art at the time the instant application was filed would have been motivated to incorporate an inert lubricant, such as talc, stearic acid, magnesium stearate, calcium stearate, silica and PEG, in an amount from about 0.25% to about 5.0% by weight, into the microparticle of the Yalkowsky '026 patent, so as to promote uniform distribution of the inert components and the medicament thereby effectuating content uniformity among the manufactured tablets, as reasonably suggested by the Maish '399 patent (column 3, lines 9-11).

With respect to claims 4-6 of the instant application, the Yalkowsky '026 patent teaches a tablet formed from direct compression of an inert, pharmacologically acceptable, excipient microparticle having a pharmaceutically active material uniformly deposited thereon. The Yalkowsky '026 patent does not explicitly teach a particular hardness, friability and disintegration time. However, the Maish '399 patent teaches a tablet formed from a free-flowing direct compression microparticulate tableting composition comprising an inert diluent, an inert lubricant, and a medicament, wherein said free-flowing direct compression microparticulate tableting composition is subjected to direct compression,

thereby yielding a tablet having a hardness of 16.0 daN and 18.9 daN, a friability of 0.2% and 0.2%, and a disintegration time of 1.5 seconds and 4.0 seconds, respectively (column 7, example 9, lines 30-50). It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to utilize the direct compression method for making compressed tableting containing a medicament, as taught in the Maish '399 patent, because the Yalkowsky '026 patent teaches that the direct compression microparticulate tableting composition may be formed into tablets by the well-known direct compression method for making compressed tablets containing drugs. One of ordinary skill in the art at the time the instant application was filed would have been motivated to utilize the direct compression method taught in the Maish '399 patent for making compressed tablets containing a medicament, as taught in the Yalkowsky '026 patent, since the Maish '399 patent teaches utilizing a direct compression for obtaining compressed tablets having a desired hardness, friability and disintegration time. One of ordinary skill in the art at the time the instant application was filed would have had a reasonable expectation of success in utilizing the direct compression method for making compressed tableting containing a medicament as taught in the Maish '399 patent, since the inert diluent (i.e., starch, lactose and the like) and the inert lubricant (i.e., talc) of the Maish '399 patent, are identical to the inert excipients (i.e., lactose, starch and/or talc) taught in the Yalkowsky '026 patent.

With respect to claims 13 and 16 of the instant application, the Yalkowsky '026 patent teaches direct compression of an inert, pharmacologically acceptable, excipient microparticle having a pharmaceutically active material uniformly deposited thereon. However, the Yalkowsky '026 patent does not explicitly teach a particular compression force. Although the Maish '399 patent teaches a tablet formed from a free-flowing direct compression microparticulate tableting composition comprising an inert diluent, an inert lubricant, and a medicament, wherein said free-flowing direct compression microparticulate tableting composition is subjected to a direct compression pressure of

1100 pounds per square inch (psi) and 2100 psi (column 7, example 9, lines 30-50), the Maish '399 patent likewise does not explicitly teach a direct compression force in units of kilonewtons (kN). Therefore, neither the Yalkowsky '026 patent nor the Maish '399 patent explicitly teach a tablet formed from a particular direct compression force of between 5 kN and 50 kN. However, while neither the Yalkowsky '026 patent nor the Maish '399 patent explicitly teach a tablet formed from a particular direct compression force of between 5 kN and 50 kN, it is well within the purview of the skilled artesian to determine the optimal direct compression force by systematically adjustment during the course of routine experimentation. One of ordinary skill in the art at the time the instant application was filed would have been motivated to systematically adjust the direct compression force during the course of routine experimentation so as to obtain a tablet having a desired hardness, friability and disintegration time. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 105 USPQ 233, 235 (CCPA 1955). "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." See *Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Examiner's Response to Applicants' Remarks

Although no arguments are currently presented within the instant Response, which was filed on August 17, 2006, in an effort to advance compact prosecution, Applicants' arguments, as set forth in the previous Non-Compliant Amendment filed May 24, 2006, have been considered in light of the claims as currently amended. However, said arguments are nevertheless deemed unpersuasive. Applicants' claim amendments necessitated the new grounds of rejection as set forth hereinabove.

1. 35 U.S.C. § 102(b) rejection of claims 1, 7 and 10 based on the Yalkowsky '026 patent.

Applicants' arguments with respect to the rejection of claims 1, 7 and 10 under 35 U.S.C. § 102(b) as being anticipated by the Yalkowsky '026 patent are moot in light of the withdraw of said rejection within the instant Official Action due to the instant claim amendment incorporating the limitations of dependent claim 2 into independent claim 1.

2. 35 U.S.C. § 103(a) rejection of claims 2-6, 8, 9 and 11-16 based on the Yalkowsky '026 patent in view of the Maish '399 patent.

Applicants' arguments with respect to the rejection of claims 2-6, 8, 9 and 11-16 under 35 U.S.C. § 103(a) as being unpatentable over the Yalkowsky '026 patent in view of the Maish '399 patent are moot in light of the withdraw of said rejection within the instant Official Action due to the instant claim amendment canceling dependent claim 2 and incorporating the limitations of dependent claim 2 into independent claim 1.

3. 35 U.S.C. § 103(a) rejection of claims 1 and 3-16 based on the Yalkowsky '026 patent in view of the Maish '399 patent.

Applicants' arguments, as set forth on pages 6-9 of the aforementioned Non-Compliant Amendment, will be addressed to the extent of which they pertain to the instant 35 U.S.C. § 103(a) rejection of claims 1 and 3-16 based on the Yalkowsky '026 patent in view of the Maish '399 patent.

Applicants argue on pages 6 and 7 of the aforementioned Non-Compliant Amendment, that the Yalkowsky '026 patent does not teach spherical particles having a uniform size. In response to Applicants' arguments, the Yalkowsky '026 patent teaches fine inert, pharmacologically acceptable, excipient microparticles, which are presumed to be spherical in nature by one of ordinary skill in the

art absent a showing to the contrary, having uniformly deposited thereon droplets of substantially uniform size comprising a pharmaceutically active material (column 1, lines 5-23; column 3, lines 1-33; column 4, lines 45-54; column 6, lines 43-44); wherein although a very large number of said pharmaceutically coated microparticles have particle diameters between 0.5 μm to about 10 μm, the variation of the particle diameters is not precisely controllable and is variable up to about 100% for a preferred spraying time of at least about 10 minutes (column 4, lines 7-19; column 6, lines 41-62).

Applicants argue on pages 7-9 of the aforementioned Response, that the Maish '399 patent does not teach an inert particulate having a low concentration of a pharmaceutically active material coated thereon. In response to Applicants' arguments, the Maish '399 patent is not being relied upon for teaching these claim limitations, as said limitations are taught by the Yalkowsky '026 patent as discussed in greater detail hereinabove.

Applicants argue on pages 8 and 9 of the aforementioned Response, that the Maish '399 patent does not provide motivation to modify the spraying time and thus particle sizes of the Yalkowsky '026 patent since the particle sizes taught in the Maish '399 patent refer to the size of the lubricant particles and not the cellulose particles. In response to Applicants' arguments, the Maish '399 patent teaches a free-flowing direct compression microparticulate tableting composition comprising an inert diluent such as cellulose and starch having mean particle diameters ranging from about 70 μm to about 200 μm (column 1, lines 66-68; column 2, lines 1-5 and 50-54; column 4, lines 26-29 and 38-45; claims 1, 3 and 5).

Applicants argue on pages 8 and 9 of the aforementioned Response, that the Official Action fails to provide a motivation for prolonging the spraying time and thus increasing the particle size of the microparticulate composition of the Yalkowsky '026 patent and that merely increasing the spraying time would in fact produce particles in the instantly claimed range. In response to Applicants'

arguments, the Yalkowsky '026 patent teaches that although a very large number of said pharmaceutically coated microparticles have particle diameters ranging from about 0.5 μm to about 10 μm, the variation of the particle diameters is not precisely controllable and is variable up to about 100% (i.e., from about 50 μm to about 1000 μm) for a preferred spraying time of at least about 10 minutes, and more specifically from about 10 minutes to about 30 minutes (column 4, lines 7-19; column 6, lines 41-62). It would have been prima facie obvious to one of ordinary skill in the art that a spraying time from about 10 minutes to about 30 minutes would produce particle diameters ranging from about 100 μm to about 2000 μm, as instantly claimed. As previously discussed, one of ordinary skill in the art would have been motivated to increase the spraying time and thus increase the particle size of said microparticles, so as to produce a free-flowing composition for facilitating large scale industrial manufacturing processes and effectuating content uniformity among the manufactured tablets by promoting uniform distribution of the inert components and the medicament, as reasonably suggested and taught by the Maish '399 patent (column 1, lines 66-68; column 2, lines 1-5 and 50-54; column 4, lines 26-29 and 38-45; claims 1, 3 and 5).

Conclusion

Applicants' claim amendments necessitated the new grounds of rejection presented in this Official Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from

the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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